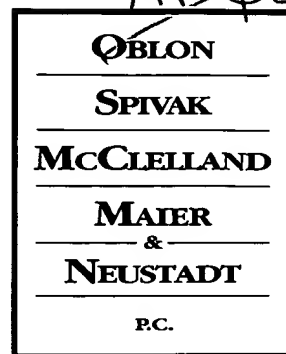




Docket No.: 216110US0PCT



ATTORNEYS AT LAW

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

RE: Application Serial No.: 09/926,586
Applicants: Anna BERGGREN, et al.
Filing Date: November 21, 2001
For: NEW COMPOSITION
Group Art Unit: 1761
Examiner: PRATT

SIR:

Attached hereto for filing are the following papers:

APPEAL BRIEF

Our credit card payment form in the amount of \$500.00 is attached covering any required fees. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the above-noted documents, including any fees required under 37 C.F.R. 1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. 1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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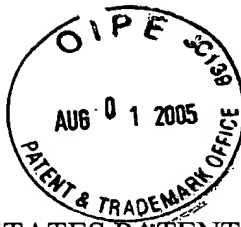
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DOCKET NO: 216110US0PCT



IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :
ANNA BERGGREN, ET AL. : EXAMINER: PRATT, HELEN F
SERIAL NO: 09/926,586 :
FILED: NOVEMBER 21, 2001 : GROUP ART UNIT: 1761
FOR: NEW COMPOSITION :

APPEAL BRIEF

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

This Brief is submitted in response to the rejection dated December 29, 2004.

REAL PARTY OF INTEREST

The real party of interest herein is Probi AB, Lund, Sweden.

08/02/2005 JADD01 00000019 09926586

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RELATED APPEALS AND INTERFERENCES

To the best of Appellants' knowledge, there are no other appeals or interferences which will directly affect or be directly affected by, or have a bearing on, the Board's decision in this appeal.

STATUS OF CLAIMS

Claims 15, 16, 18-25, 29, 36 and 37 are active and remain rejected in this application.

STATUS OF AMENDMENTS

In the After Final Amendment filed April 27, 2005, Claim 15 was amended to include the micronutrients from Claim 17 and certain claims were cancelled. This amendment was entered (see Advisory Action mailed May 10, 2005). Accordingly, there are no outstanding amendments in this case.

SUMMARY OF CLAIMED SUBJECT MATTER

The present invention is based on the discovery that certain types of viable lactobacilli have a positive effect on human intestinal mucosa and therefore are particularly useful in a sports drink "which in addition to a nutrient and fluid supplementation before or after physical activity in order to build up and recover, respectively, the energy and fluid levels of the body, also relieves the symptoms of stress." (See page 3, lines 1-4 of the present application). On this basis, the attached claims are presented, which as provided in Claim 15 require:

- (1) one or more micronutrients selected from a specified group; and

(2) viable lactobacilli having a positive effect on human intestinal mucosa.

REJECTIONS TO BE REVIEWED ON APPEAL

1. The first rejection to be reviewed on appeal is of Claim 14 under 35 U.S.C. § 102(a) in view of Connolly.
2. The second rejection to be reviewed on appeal is of Claims 15, 25, 33, 34, 35, 36, and 37 under 35 U.S.C. § 103(a) in view of U.S. patent publication 2002/0090416 (“Connolly”) combined with WO 98/46091 (“Kurppa”).
3. The third rejection to be reviewed on appeal is of Claims 16-21, 26-29 and 32 under 35 U.S.C. § 103(a) in view of Connolly and Kurppa, combined with WO 89/08405 (“Mollin”) and Wilkes (“Food Product Design”).
4. The fourth rejection to be reviewed on appeal is of Claim 24 under 35 U.S.C. § 103(a) in view of Connolly Kurppa, Mollin, and Wilkes combined with WO 98/05343 (“Masuyama”).
5. The fifth rejection to be reviewed on appeal is of Claims 22, 23, 30 and 31 under 35 U.S.C. § 103(a) in view of Connolly Kurppa, Mollin, Wilkes, and Masuyama combined with U.S. patent no. 6,051,236 (“Portman”).

ARGUMENT

Rejection #1

The rejection of Claim 14 under 35 U.S.C. § 102(a) in view of Connolly is not applicable in light of the fact that Claim 14 is not pending in this application.

Rejection # 2

Several basic factual inquiries must be made in order to determine obviousness or non-obviousness of claims of a patent application under 35 U.S.C. §103. These factual inquiries are set forth in Graham v. John Deere Co., 383 U.S. 1, 17, 148 USPQ 459, 467 (1966):

Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness of the subject matter is determined.

The specific factual inquiries set forth in Graham have not been considered or properly applied by the Examiner in formulating the rejection of the subject claims. Particularly, the scope and content of the prior art and the level of ordinary skill in the pertinent art were not properly determined, demonstrated and applied to the claimed invention. In the present case, proper consideration of the factual inquiries demonstrates the non-obviousness of the claimed invention.

As will be apparent after reviewing the comments below, Claims 15, 25, 33, 34, 35, 36, and 37 would not have been obvious in view of Connolly and Kurppa for the simple reason that the combination of these two publications fails to (1) describe or suggest a sports drink as claimed; and (2) fails to provide any disclosure or suggestion for the selection of viable lactobacilli having a positive effect on human intestinal mucosa. Further details on these points follow.

As a basis for this rejection, the Office has alleged that Connolly describes a sports drink “because the reference discloses a liquid and the claimed bacteria.” (Page 2 of the final Office Action). This is a mischaracterization of Connolly. In fact, the entire disclosure of Connolly is to prepare a powdered or **dried** preparation of milk protein with probiotic bacteria. For example, in describing the process for making this protein concentrate in paragraphs [0059] and [0068], Connolly describes preparing a culture in which the organisms are grown to which milk proteins are added to a desired concentration. Connolly describes “then one **spray dries** the fluid inoculated concentrate under a gentle, low heat condition, to protect the organisms, and turn it into a **powder**.” (Emphasis provided).

Thus, it is clear that Connolly does not describe anything that could be construed as a sports drink as claimed. While Kurppa describes various ingredients in a drink powder composition there is nothing in Kurppa which suggest the inclusion of lactobacilli nor is there anything in Connolly which suggests including any of the components in Kurppa. Without using the present claims as a guide, there simply is no motivation to combine these two disclosures because each is directed to a distinct solution to address different problems. On this basis alone, the rejection should be reversed. However, there is a further reason why the rejection based on Connolly and Kurppa fails to render Claims 15, 25, 33, 34, and 35 obvious.

Connolly also describes a number of possible probiotic bacteria, several of which are listed in paragraphs [0062]-[0068]. Connolly does not exemplify any specific strain and certainly does not describe or suggest selecting the Lactobacilli as claimed. In fact, among this general listing of certain Lactobacillus and Bifidiobacterial species that Connolly describes, Connolly does not even hint at the variation that occurs in various strains of these bacterial species or provide any reason to look for those Lactobacilli as claimed. As a result, Connolly neither describes nor suggests the desire to select “viable Lactobacilli having a positive effect on human and intestinal mucosa” (Claim 15) from the number of possible

probiotic organisms Connolly describes. As already noted, and conceded by the Office, Kurppa does not describe or suggest any lactobacilli and thus adds nothing to this rejection in this regard.

Even assuming for arguments sake that one would have combined these two disclosures, the combination of publications simply does not suggest selecting viable lactobacilli as those claimed in the present set of claims. As stated throughout the specification, the advantages of the claimed sports drink are to provide, in addition to nutrients and fluid supplementation during physical activity, positive effects on the human intestinal mucosa. Not all microorganisms have such features because they would not survive in such a sports drink together with the other components, which as stated in the claim must be viable. Furthermore, the combination of these two publications fails to suggest the surprising advantages of the claimed sports drink:

It has now surprisingly been shown that viable Lactobacilli can be mixed with micronutrients, carbohydrates, salts and proteins, without negative effects on e.g., antioxidants, to a beverage having a good taste and a shelf-life. page 3, lines 4-8 of the present specification.

"Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combinations". In re Geiger, 815 F.2d 686, 2 USPQ 2d 1276, 1278 (Fed. Cir. 1987). The Patent Office can only satisfy its burden to establish a *prima facie* case of obviousness "by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." In re Fine, 837 F.2d 1071, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1988). For the reasons set forth above, such teachings, suggestions or incentives are missing here.

By combining the above references, the Examiner has not considered them as a whole, as she is required to do. In re Fine, *supra*. The Examiner has not established that a

one would have prepared a sports drink with micronutrients and viable lactobacilli as claimed. It is only with Applicants' disclosure as a guide that one skilled in the art would arrive at the presently-claimed invention.

As this rejection was applied to Claims 33, 34, and 35, it is no longer applicable in light of the fact that Claims 33, 34, and 35 have been cancelled.

The points discussed above regarding the rejection based on the combination of Connolly and Kurppa as it applied to Claim 15 also applies equally to Claims 25, 36, and 37 and further in view of the following.

Claim 25 is directed to a method of treating stress symptoms, gastrointestinal disturbances, and lesions of the mucosal membrane of the intestines in an individual in need thereof comprising providing the sports drink claimed in claim 15. As discussed in detail above, since the combination of Connolly and Kurppa fails to provide the requisite disclosure to render obvious Claim 15, the method of Claim 25 is also not obvious in view of these two publications. (see *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995)).

Claim 25 would also not be obvious in view of the combined teachings of the cited publications because the publications fail to describe or suggest administration of the sports drink of claim 15 with the specific intent of treating stress symptoms, gastrointestinal disturbances and lesions of the mucosal membrane in an individual in need thereof. The presence of the “in need thereof” limitation sets forth an intentional purpose (treating stress symptoms, gastrointestinal disturbances and lesions of the mucosal membrane) which must be described in the applied prior art for the rejection to be maintained. Because the cited prior art doesn’t even describe or suggest the claimed sports drink, how can it possibly describe the use of the sports drink for a purpose other than that intended in the present

claims. Accordingly, these publications do not render the method claimed in Claim 25 obvious.

The Court of Appeals of the Federal Circuit, has stated most recently in *Jansen v. Rexall Sundown, Inc.* (68 U.S.P.Q. 2d 1154), “in need thereof” language is not satisfied if the active ingredient is administered for a purpose other than the claimed purpose. In *Jansen*, the Court held that treating a patient “**in need thereof**” with the goal of treating a macrocytic-megaloblastic anemia distinguishes the claim from what was known previously. In particular, it is also noted that based on the treatment of an individual “in need thereof,” the Patent Office granted claims over prior art that taught the combination of folic acid and vitamin B₁₂ for purposes other than the claimed method.

This decision in *Jansen* followed a series of cases from the C.A.F.C. and the C.C.P.A., namely *Rapoport v. Dement*, 59 U.S.P.Q.2d 1215 (Fed. Cir. 2001); *In re Marshall*, 198 U.S.P.Q. 344, 346 (CCPA 1978); and *In re Shetty*, 195 U.S.P.Q. 753, 252 (CCCPA 1977). In *Rapoport*, the Court was faced with a claim directed to a “method for treatment of sleep apneas using an azapirone compound. The Court held that this new use was patentable over a reference which taught use of the same azapirone compound for the treatment of “anxiety” which was a symptom of sleep apnea. Indeed, the reference even mentioned the possibility of administering the azapirone compound to patients suffering from sleep apnea but the Court noted that this was for the purpose of treating anxiety in such patients not for the purpose of treating the sleep apnea disorder itself.

The situation in the present application is similar to the situations presented to the Court in *Jansen* and *Rapoport*. Here, the prior art does not describe using a sports drink comprising micronutrients and viable lactobacilli having a positive effect on human intestinal mucosa for the purpose of treating stress symptoms, gastrointestinal disturbances and lesions of the mucosal membrane as claimed in Claim 25. *Connolly*, describes generating better

overall health, providing a higher ratio of anabolism, more muscle tissue growth in an athlete and others (see page 2, [0016—[0023])). Kurppa describes a composition for “retaining the bodily vigor of sportsmen” (page 2). Thus, it is clear that the combination of these two publications cannot render the invention claimed in Claim 25 obvious because the publications simply fail to describe the intent of treating subjects in need thereof as claimed.

Rejection #3

As this rejection was applied against Claims 17, 26, 27 and 32, the rejection is no longer applicable as Claims 17, 26, 27 and 30 have been cancelled.

As this rejection was applied against Claims 16, 18-21, and 29, the rejection is untenable because Claims 16, 18-21 and 29 would not have been obvious in view of the combination of Connolly, Kurppa, Mollin, and Wilkes for at least the reasons discussed above noting that each of Claims 16, 18-21 and 29 ultimately depend from independent Claim 15. Furthermore, Claims 16, 18-21 and 29 would not have been obvious in view of the combination of these four publications based simply on the fact that neither Mollin nor Wilkes provides any further evidence that one would have selected “viable lactobacilli having a positive effect on human intestinal mucosa” and combining the same with micronutrients as claimed. Further details follow.

Mollin simply describes a health drink for horses containing various nutrients and Lactobacilli (see page 2, lines 11-17)—noting that the claims require lactobacilli having a positive effect on humans. In fact, Mollin describes that the Lactobacilli useful for the invention must meet certain characteristics to be suitable for the administration to horses for the “prevention of diarrhoe” (page 2, lines 18-21 and page 3, lines 23 to page 4, line 13) but does not describe anything relating to the positive effect on human intestinal mucosa as claimed.

Certainly it can be appreciated that the digestive tract and general physiology between horses and humans are different. Further, treating diarrhea in horses has nothing to do with providing a positive effect on intestinal mucosa in humans undergoing physical activity. As a result, the disclosure of Mollin is inapplicable to the claimed invention and further would not have been combined with the other references because Mollin is providing a solution to an entirely different problem, i.e., treatment of horses.

Wilkes simply describes that minerals are used in beverages to improve athletic performance but provides no further suggestion for the selection of lactobacilli having a positive effect on human intestinal mucosa in the claimed combination.

In view of the above, it is readily apparent that the besides the fact that the publications would not have been combined, even in combination Mollin, Wilkes, Connolly and Kurppa fail to suggest or provide any reasonable guidance to select lactobacilli and combining the same with additives and micronutrients as claimed.

Rejection #4

Claim 24 would not have been obvious in view of Mollin, Wilkes, Connolly and Kurppa further in view of Masuyama for at least the reasons set forth above concerning Claim 15, noting that Claim 24 depends there from. Claim 24 is directed to a tablet for a preparation of a sports drink according to claim 15 which includes the micronutrients and freeze-dried, viable lactobacilli having a positive effect on human intestinal mucosa.

Masuyama simply describes forming tablets. However, when combined with Mollin, Wilkes, Connolly and Kurppa, there is still nothing which provides any reasonable suggestion or provides any motivation to select viable lactobacilli having a positive effect on human intestinal mucosa and combining the same with additives and micronutrients as claimed.

Rejection #5

As this rejection was applied against Claims 30 and 31, the rejection is no longer applicable as Claims 30 and 31 have been cancelled.

As this rejection was applied against Claims 22 and 23, the rejection is untenable because Claims 22 and 23 would not have been obvious in view of the combination of Connolly Kurppa, Mollin, and Wilkes for at least the reasons discussed above noting that each of Claims 22 and 23 ultimately depend from independent Claim 15. Furthermore, Claims 22 and 23 would not have been obvious in view of the combination of these four publications based simply on the fact that Portman does not provide any further evidence that one would have selected “viable lactobacilli having a positive effect on human intestinal mucosa” and combining the same with micronutrients as claimed.


Claims 22 and 23 require whey proteins in a certain concentration range in addition to the viable lactobacilli and micronutrients as set forth in Claim 15. While Portman describes using whey proteins, Portman describes nothing of particular relevance to the claimed invention. Thus, since Connolly Kurppa, Mollin, and Wilkes fail to provide the requisite disclosure for the claimed sports drink including lactobacilli, the combination of Connolly Kurppa, Mollin, and Wilkes with Portman also fails to provide any, let alone the requisite, disclosure for the claimed sports drink.

CONCLUSION

Accordingly, in view of the above remarks and reasons explaining the patentable distinctness of the presently appealed claims over the applied prior art, Appellants request that the final rejections be REVERSED.

Respectfully submitted,

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Appendix I (Claims)

Claims 1-14 (Cancelled).

15. (Rejected) A sports drink comprising one or more micronutrients selected from the group consisting of ascorbic acid, vitamin E, carotenoids, pyridoxine, thiamine, riboflavin, niacin, cobalamin, folacin, Q10, flavonoids, copper, magnesium, manganese, selenium, zinc and chromium in combination with additives for sports drinks, and viable lactobacilli having a positive effect on human intestinal mucosa.

16. (Rejected) A sports drink according to claim 15, comprising one or several strains of *Lactobacillus acidophilus*, *Lactobacillus casei*, *Lactobacillus fermentum*, *Lactobacillus paracasei*, *Lactobacillus plantarum*, *Lactobacillus reuteri*, and *Lactobacillus rhamnosus* in a therapeutically effective amount.

17. (Cancelled).

18. (Rejected) A sports drink according to claim 15, comprising per 1000 g

ascorbic acid	500-1200 mg
vitamin E	250-375 mg
β -carotene	15-25 mg
pyridoxine	15-25 mg
sodium	20-60 mg
potassium	60-100 mg
copper	0.5-1.5 mg
magnesium	120-175 mg

manganese	1-3 mg
selenium	0.05-0.15 mg
zinc	5-15 mg

19. (Rejected) A sports drink according to claim 15, which comprises proteins, optionally in combination with amino acids.

20. (Rejected) A sports drink according to claim 19, wherein the protein is a whey protein or whey protein hydrosylate.

21. (Rejected) A sports drink according to claim 15, which comprises carbohydrates having a low glycemic index, optionally in combination with carbohydrates of a high glycemic index.

22. (Rejected) A sports drink according to claim 15, comprising per 1000 g

whey proteins	15-60 g
carbohydrates	40-150 g
micronutrients	1-2 g
probiotic strain of	$5 \cdot 10^7 - 5 \cdot 10^8$ cfu/ml
Lactobacillus	

23. (Rejected) A sports drink according to claim 15, comprising per 1000 g:

whey protein isolate	15-60 g
mono- and disaccharides	40-150 g
micronutrients	1-2 g

L. plantarum DSM 9843

$5 \cdot 10^7$ - $5 \cdot 10^8$ cfu/ml

24. (Rejected) A tablet for the preparation of a sports drink according to claim 15 in vivo or in vitro, comprising micronutrients in combination with freeze-dried, viable lactobacilli.

25. (Rejected) A method of treating stress symptoms, gastrointestinal disturbances, and lesions of the mucosal membrane of the intestines in an individual in need thereof, comprising providing the sports drink according to claim 15 to the individual wherein the sports drink is ingested by the individual in an amount sufficient to treat stress symptoms, gastrointestinal disturbances and lesions of the mucosal membrane.

Claims 26-28. (Cancelled).

29. (Rejected) A sports drink according to claim 19 ~~claim 27~~, which comprises carbohydrates having a low glycemic index, optionally in combination with carbohydrates of a high glycemic index.

Claims 30 -35 (Cancelled).

36. (Rejected) The sports drink according to claim 15, wherein the viable lactobacilli are selected from the group consisting of *Lactobacillus plantarum* 299, *Lactobacillus plantarum* 299v, *Lactobacillus rhamnosus* 271, *Lactobacillus rhamnosus* GG, *Lactobacillus casei rhamnosus* LB 21, *Lactobacillus casei* Shirota, *Lactobacillus johnsonii* Lj1 and *Lactococcus lactis* L1a.

37. (Rejected) The sports drink according to claim 36, wherein the viable lactobacilli are *Lactobacillus plantarum* 299v.

Application No. 09/926,586
Appeal Brief

Appendix II (Evidence)

None